

UNIVERSITY OF MICHIGAN
ORAL CONSENT SCRIPT TO BE PART OF A RESEARCH STUDY
[This will be done with people who are screened and deemed as eligible.]

Congratulations, you are eligible for the study. Now I will go over the information about the study that will help you decide whether you will join. Feel free to ask me questions and interrupt me as I go.

1. Purpose of the study

The purpose of the study is to understand if an internet educational program we developed can help lift people's spirits and make them feel more socially connected. We also want to see how easy it is to use the program.

This study is completely separate from the services you receive from [insert the name of the referring agency]. Participation in this research project will not affect the services you receive from [insert the name of the referring agency].

2. What is the study about?

Seniors sometimes feel down or isolated. It can be hard to get the help they need while staying home. We want to see if delivering psychological services online is a good idea.

3. What will happen if you take part in this study?

Participants will be randomly assigned to two groups. One group of participants will be asked to do an online program right away, and the other group will wait for 10 weeks before they are offered the program. While they are waiting, they will receive a brief check-in call from research staff every week for 10 weeks. After 10 weeks of waiting, they will be provided with the online program. If you agree to participate, you must agree to be randomly assigned to either group.

The online program involves watching video clips and do some interactive exercises, like answer questions or reflect on your life experience. The program has 9 lessons. Each takes about 25 to 30 minutes.

We will give you 10 weeks to try the program. You don't have to finish the program by then. You can watch the lessons wherever and whenever you want. If you don't have a device or internet, we will provide a tablet and internet free of charge. Please understand that you don't get to keep the tablet afterwards. We will set up and mail you the tablet and accessories to your home address with a return shipping label. At the end of the 10 weeks, we will arrange for UPS pick up for you to ship back our tablet.

Aside from trying out the program, we will also invite you to do three surveys. One shortly after you agree to participate, the second one at the end of 10 weeks, and a third one at 10 weeks after. We may need to use a digital recorder to record your answers.

We record your answers because it would be difficult to remember everything you say to us. We will transcribe the recording and then destroy them. We won't share your voice with anyone other than the study team members. You must agree to be recorded to participate in this study. We will always let you know and get your verbal consent again before we start recording you.

Each survey will take about 40 minutes. We will schedule the survey at a time that is convenient for you. Depending on your preference, we will do the surveys either over the phone, through an online survey, or online conference like Zoom.

All the study activities will occur remotely. That means you will do them at home or wherever you like. You don't need to travel anywhere to participate.

4. How could you benefit from this study?

You will get free online lessons that may help lift your spirits and make you more active and connected with others. It might increase your sense of self-efficacy and help you feel more independent, less worried, and feel less like a burden. It may also improve your quality of life. These benefits may last after the program is finished. However, please understand that the lessons you will be doing are previously untested. We don't know for sure that it will help you.

5. What risks will I face by taking part in the study?

There are some risks you might experience from being in this study. During the study we ask personal questions. Some of the questions could make you feel uncomfortable. You could become upset or even reveal to us that you feel suicidal. There is also a risk of loss of privacy. We will try to minimize these risks by always being sensitive to your feelings. You may also choose not to answer questions you don't feel comfortable answering. If it is revealed to us that you have suicidal feelings or thoughts, a clinical social worker or other healthcare professional will be contacted. We will also encourage you to seek the help from other health care providers or services.

6. How will we protect your information?

To protect your privacy, we will not include any information that could directly identify you. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project. We will place this information in a locked, secure space.

7. Who can see my data?

Only people authorized can see your data. These people are the researchers directly involved in this study and trained research assistants.

8. What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future research. Your name and other information that can directly identify you will be deleted from the research data collected as part of the project within 12 months after your last interview is completed. We will not share your research data with other researchers. You don't have to agree to have your data retained to participate in this study.

9. How will we compensate you for being part of the study?

You will be paid \$30 for completing the first survey. You will receive \$50 for completing the longest survey (second assessment for experimental group and third for the waiting list control). You will receive \$20 for completing the shortest survey (third for the experimental group and second for the control group). In total, you will be paid up to \$100 for participation. All payments will be made via check, cash or a gift card.

10. Your participation in this study is completely voluntary

It is totally up to you to decide to be in this research study. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, we will retain your data up to the point of withdrawal. Simply give us a call if you wish to end your participation early. At times, we may need to end your participation if we believe it is not in your best interest to stay in the study, or that your condition changes and requires treatment that is not allowed while taking part in the study.

11. What if I become ill during the study?

If you become ill or have significant decline that is not caused by your study participation, we will work with you and your case manager to determine whether an early withdrawal is necessary. We may terminate your participation early if we deem it is not at your best interest to continue. You are always free to withdraw early no matter what the reason is.

Do you have any questions about what I told you?

[Answer questions, if any]

10. Contact information

Now I want to share our contact information. Could you get a pen and a piece of paper to write down the information I am about to share?

If you have any questions about this study, you may contact Dr. Xiang at 734-763-6581. Our mailing address is 1080 S University Ave, Ann Arbor, MI, 48109.

If you have any questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researchers, you may contact

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board
2800 Plymouth Road
Building 520, Room 1169
Ann Arbor, MI 48109-2800
Phone: (734) 936-0933 or toll free, (866) 936-0933
Email: irbhsbs@umich.edu

Do you have any questions about what I told you?

[Answer questions, if any]

Consent to be a part of the research study:

Do I have your verbal consent to participate in this study? Remember, like we discussed earlier, we may need to use a digital recorder to record your answers. By giving me your consent, you also agree to be tape recorded during the interview.

[If so, ask them to read the following sentence and ask permission to record their verbal consent]:

“My name is [insert subject name], and I consent to participate in this study.”

[For office use only, document whether a verbal consent is obtained and recorded, person who obtained the consent, and date.]

Format preferences:

We also offer this program in virtual groups. This means that instead of you doing the lessons on your own, you will join an online group and do the sessions together. Our research staff will host online meetings with a small group of seniors ranging from 4 to 6 people. You will be able to see each other on the computer and talk to each other. You will watch the lessons and discuss things with this small group. You will meet once a week for 10 weeks. If a group session becomes available, would you prefer to do this program with the virtual group or on your own? Right now, we just want to record your preference. The group session has limited spots so we cannot guarantee that you will be able to attend the group sessions. However, we will always honor your preference not to attend the group sessions.

Record their preference.

Consent to have their data retained for future use:

Do I have your verbal consent to retain your data for future use?

“My name is [insert subject name], and I consent to have my data retained for future use.”

[For office use only, document whether a verbal consent is obtained and recorded, person who obtained the consent, and date.]